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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08 832,443	04 03 1997	STEPHEN D. WOLPE	1331-222C#M#	1001

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED 12 18 2002

36

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 832 443	Applicant(s) WOLPE
Examiner SAUNDERS	Group Art Unit 1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 6/3/02 & 7/19/02
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 47-52, 91-102 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 47-52, 91-94 is/are allowed.
- ☒ Claim(s) 95-102 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).
- *Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

The amendment of 6/3/02 (Paper 33) has been entered. Claims 47-25 and 91-102 are pending and under examination.

The text of those selections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Applicant's amendment has overcome previously stated 112 paragraph rejection; however, the amendment has necessitated the following new rejection under this statute.

Claims 95-99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 95, at line 5 the Markush group language is improper. At the right hand end of the line, applicant must insert --of--.

Applicant's amendment has necessitated the following rejection of new claims 100-102.

Claims 100-102 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite new matter by virtue of reciting, "consisting essentially of".

Applicant's disclosure has not specifically set forth what is considered to be essential to the claimed method of "stimulating" and what is not essential to this method. That is, there has been no teaching of what, in addition to INPROLs and/or opiate

Art Unit: 1644

compounds, can be contacted with the stem cell, and no teaching of what procedures in addition to contacting, can be conducted while maintain^{ing} the "essential" nature of the claimed method of stimulating. Since applicant has not disclosed what is and what is not essential, the claims recite new matter.

Applicant's amendment has overcome the previously stated 102(b) or (e) rejections over Rosenthal et al. (WO 95/24213 or U.S. 5,681,219), upon the interpretation that claim language reciting "a polypeptide having the sequence of amino acids..." is closed language. This was the policy of the USPTO at the time this application was filed. If the applicant places a different interpretation upon the claim language, he is required to state so in the next response.

New claims 100 and 102 are rejected over Rosenthal et al. as follows.

Claims 100 and 102 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Rosenthal et al. (WO 95/24213 or U.S. 5,631,219).

The teachings of Rosenthal et al. have been noted in Paper 32.

Applicant's response in Paper 33 has indicated that new claims 100 and 102 are free of the prior art because the claim language reciting "consisting essentially of" would exclude the presence of the heme groups normally associated with the polypeptide chains. The examiner disagrees for the following reasons.

1) The phrase "consisting essentially of " modifies the claim step of "contacting", not the nature of the INPROL selected to conduct the method.

2) Even if "consisting essentially of " were considered to modify the selected INPROL compounds, the rejection would remain because "consisting essentially of" is

Art Unit: 1644

not closed language. Rather this language permits the inclusion of any additional components which would not essentially change the nature of or activity of the compounds for their intended, disclosed use. Instantly applicant has disclosed that the compositions can be "multimers, with or without heme" (specification page 21, line 3). Thus, the presence of heme moieties in the multimers would not change the essential nature of the hemoglobin employed in the claimed process. Therefore "consisting essentially ^{of} language permits the presence of heme.

3) Rosenthal et al. 's hemoglobin compositions do not necessarily contain hemoglobin, since they teach that the hemoglobin polypeptides merely "preferably" have the ability to incorporate heme (col.13, lines 51-52).

Applicant's urgings filed on 6/3/02 have been considered, but are unconvincing of patentability.

The information disclosure statement filed 7/19/02 fails to comply with 37 CFR 1.98 (a) (1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP 706.07 (a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136 (a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1644

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9307

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Saunders/DL

December 12, 2002

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/1644